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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,043	02/17/2004	William H. Fleming	6122-67949-01	8393
24197 7590 10/06/2008 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER STEPHENS, JACQUELINE F	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 10/06/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,043	Applicant(s) FLEMING, WILLIAM H.	
	Examiner Jacqueline F. Stephens	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In view of the Pre-Appeal Request filed on 4/29/08, PROSECUTION IS HEREBY REOPENED. New grounds of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

Response to Arguments

2. Applicant's arguments filed 2/11/08 have been fully considered and they are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3761

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

As to claims 1, 2, 10-12, 18, 20, 21, 24, 25, 33, 49, and 50, Sartorio discloses a method for absorbing leakage comprising positioning a non-adhesive absorbent pad. Sartorio does not specifically teach the pad is used against the anal orifice, however, Sartorio teaches the pad may be formed in a variety of shapes (Figures 5-7 and col. 3, lines 3-6). Therefore, it is within the level of one of ordinary skill in the art to provide a shape that would be capable of being retained within the buttocks since the pad of Sartorio solves the same problem of absorbing bodily discharge within a body cavity. , Sartorio discloses the pad is self-retained (col. 2, lines 46-55), which indicates no adhesive is used to retain the pad. The pad is tapered to facilitate insertion between the labia and retention in the interlabial space (Abstract). Sartorio discloses the device carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent (col. 4, lines 30-50). Sartorio incorporates by reference various patents providing examples of medicaments and methods used in bacterial-treating properties (col., 4, lines 38-45).

As to claim 3, the absorbent material is a highly absorbent swellable material (col. 6, lines 3-11 and lines 33-56).

As to claims 5, 6, 13-15, 26-28, the pad has a minor portion and a major portion as claimed (Figures 5-7).

As to claims 7, 19, 44-48, 51, and 52, Sartorio discloses the pad includes an agent for absorbing odors (col. 4, lines 25-37).

As to claims 8, 9, 22, and 23, Sartorio discloses the pad carries a therapeutically effective amount of a medicinal agent for anal delivery, where it is reasonable to conclude a subject wearing such a pad is in need of the medicinal agent (col. 4, lines 30-50).

As to claims 31, 32, and 34-41, see Figures 1-8. Sartorio additionally discloses the shape can be modified to achieve maximum incontinence control (Figures 5-7, col. 3 lines 3-6).

As to claims 42 and 43, Sartorio discloses the pad carries a therapeutically effective amount of a medicinal agent for anal delivery, where it is reasonable to conclude a subject wearing such a pad is in need of the medicinal agent (col. 4, lines 30-50).

As to claims 16, 17, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sartorio USPN 6319238 in view of Okuda et al. USPN 4920045.

Art Unit: 3761

Sartorio teaches diagnostic analysis of the pad (col. 2, lines 7-10). Sartorio does not specifically disclose the step of performing a diagnostic test on the fecal material.

Okuda discloses detection of occult blood in feces for the purpose of early finding an abnormality such as cancer or ulcer in digestion organs at an early stage (col. 4, lines 4-14). It would have been obvious to one having ordinary skill in the art to provide the method of absorbing leakage and diagnostic analysis as taught in Sartoria with the step of diagnostic testing of the fecal material for the benefits disclosed in Okuda.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline F Stephens/
Primary Examiner, Art Unit 3761